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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,273	03/01/2002	John R. Gordon	4616-62430	3115

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,273

Applicant(s)

GORDON ET AL.

Examiner

Prema M Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-93 is/are pending in the application.
- 4a) Of the above claim(s) 91-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/30/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Examiner acknowledges that in preparing the Restriction claims 67-86 were correctly renumbered 60-79, respectively. Applicants have canceled claims 1-79 in the amendment of 12/2/2004. New claims 87-93 are pending in the instant application.

Election/Restriction

1. Applicant's election of Group 5 (new claims 87-90) in the reply filed on 12/2/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Furthermore, Applicants request rejoinder of the subject matter of Groups 5 and 8 (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995))), in which a new, unobvious material is used in a known process. Ochiai determined that a process was free of the prior art if it employed a product which was free of the prior art. However, only if the product claims of Group 5 are found allowable, the subject matter of Group 5 will be rejoined with the process claims of Group 8, if the process claims are of the same scope as the allowable product claims.

Claims 91-93 are withdrawn from consideration by the Examiner as drawn to a non-elected invention.

Specification

2. The drawings have been approved by the Examiner.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 87-90 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims embrace the chemokine protein as it occurs *in vivo*. However, since it would that applicants do not intend to claim a naturally occurring product, such as a chemokine circulating in a mammal, amending the claims to require the hand-of-man would obviate this rejection.

Claim rejections-35 U.S.C. § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 87-90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: (1) an isolated protein consisting of an amino acid sequence set forth in SEQ ID NO:1; (2) an isolated protein consisting of an amino acid sequence set forth in SEQ ID NO:1 wherein amino acid 30 of SEQ ID NO:1 is Gly instead of Pro; (3) an isolated protein consisting of an amino acid sequence set forth in SEQ ID NO:1 wherein amino acid 10 of SEQ ID NO:1 is Ser instead of Thr; and (4) an isolated protein consisting of an amino acid sequence set forth in SEQ ID NO:1 wherein amino acid 11 of SEQ ID NO:1 is Phe instead of his, does not reasonably provide enablement for an antagonist comprising an amino acid sequence substantially equivalent to the amino acid sequence set forth in SEQ ID NO:1. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

With respect to new claim 87, the specification does not enable a protein “substantially equivalent to.... SEQ ID NO:1”. The specification does not enable the skilled artisan to make and/or use polypeptides that have substantially the same amino acid sequence as the one disclosed. The issue here is how substantial must the sequence identity be, and what amino acids constitute this identity? The specification does not teach which residues can be conservatively substituted without affecting the functional activity of the protein. It is known to the skilled artisan that conservative amino acid substitutions outside of the active site of a protein will not affect the functional activity of the protein; however, amino acid substitutions, even conservative alterations, within the active site can inactivate the protein or change its functional activity. Absent the specific degree of sequence identity, it is unpredictable if the claimed protein would also possess the same antagonist activity as the polypeptide having the amino acid sequence of SEQ ID NO:1. Thus, without guidance as to which residues can be conservatively substituted, the skilled artisan would not be able to make and/or use polypeptides substantially equivalent to the amino acid sequence as the polypeptide having the amino acid sequence of SEQ ID NO:1.

Claim Rejections - 35 USC § 112, second paragraph

5. Claims 87-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 87 is rejected as vague and indefinite for reciting "substantially equivalent to ..SEQ ID NO:1". It is unclear how substantially identical the amino acid sequence should be, is it 50% the same, 75% the same or something else?

Claims 88-90 are rejected as vague and indefinite insofar as they depend on the above claims for their limitations.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 87 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/00601 (1997).

The reference teaches an IL-8 mutant that is an antagonist to IL-8 and comprises an amino acid sequence that is substantially equivalent to the amino acid sequence of SEQ ID NO:1 of the protein of the instant invention (see abstract; page 1, lines 15-18 and See attached Sequence comparison A). Therefore, the IL-8 mutant of the reference anticipates instant claim 87.

Conclusion

No claim is allowed.

Advisory Information

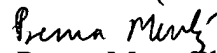
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

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Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
January 25, 2005